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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

7590 11/15/2006

Bernhard D Saxe
Foley & Lardner
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,987

Applicant(s)

MURDIN ET AL.

Examiner

Padmavathi v. Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17,20-38 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 and 26-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-17,25,36-38 and 81-83 is/are rejected.
- 7) ☒ Claim(s) 79 and 80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/17/03, 7/18/05,8/11/06,8/23/06.

DETAILED ACTION

Amendment

1. Amendment filed on 8/23/06 is entered.

Status of claims

2. Claims 9, 13 and 36-38 have been amended.

Claims 1, 2, 4-17, 20-38 and 79-83 are pending.

Claims 1, 2, 4-17, 25, 36-38 and 79-83 are under prosecution.

Claims 20-24 and 26-35 are withdrawn as non-elected inventions 37 CFR 1.142(b).

Claim Rejections - 35 U.S. C. § 112, second paragraph withdrawn

3. In view of amendment to the claims, the rejection under 35 U.S. C. § 112, second paragraph is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

4. The written description rejection of claims 1,2, 4-17, 25, 36-38 and 81-83 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant's arguments 8/23/06 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the traversal is based on a number of decisions by the Board of Patent Appeals and Interferences (BPAI) on claims that recite sequence variants or fragments, wherein the cited cases are analogous to the instant claimed invention. The BPAI's decisions provide clear guidance on applying the courts' decisions to claims that recite sequence variants or fragments and the rejections are therefore incorrect. The Examiner did not address any of these arguments.

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This argument is not persuasive because board decisions are reviewed and considered to the extent that they affirm the principles of the application of the statutory rejection set forth and each application is considered on its merits with the same principle. BPAI decisions do not carry presidential weight to the extent that they follow the principles laid down by CAFC.

For example : *in ex parte sun* the invention is drawn to a polynucleotide sequence which encodes protein tyrosine kinase sequence, the consensus sequence structure and the function is known in the art. However, applicant's invention is drawn nucleic acid molecule which encodes polypeptides comprising a fragment of seq id no:14. The structure and function of the encoded polypeptide as claimed is not known in the art or disclosed by the current specification. Therefore, this not analogous to the claimed invention. *Similarly in Ex parte Meyers*, the invention is drawn to enzyme dehydrogenase, the structure function relationships are known in the art and therefore, the comparison is not analogous to the claimed invention. similarly, contrary to applicant's arguments, the other cases cited are not analogous to the instantly claimed invention.

Therefore, the rejection is maintained as the specification fails to teach the claimed nucleic acid molecule and does not satisfy the written description guidelines because the claims are drawn to unknown nucleic acid molecules having undefined structure or function. further, recitation of open language " comprising " in the claims does not limit to the fragment consisting of 38 or 100 consecutive amino acid of seq.id.no: 1 but reads on fragments of SEQ.ID.NO: 1 plus other unknown and unlimited nucleic acids and are not supported by the present specification.

35 U.S.C. 112 scope of enablement rejection maintained

5. The scope of enablement rejection of claims 1,2, 4-17, 25, 36-38 (in part) and 81-83 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous Office action.

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Applicant states that full-length protein , fragments and fusion protein comprising fragments are routinely used to generate an immune response cites several papers.

Applicant's arguments have been fully considered but they are not deemed to be persuasive because claims are not drawn to encoded fragments consisting of seq id no:14 fragments and further because the examiner did not state that full length proteins and fragments etc would not induce immune response , rather stated the fragments as stated do not have a predictable function meaning that even if they induce an antibody response it could not be predicted that the antibody generated might recognize the full length protein.

Applicant states the examiner's statements regarding the references cited in the scope of enablement ("Niman", Reece etc) either are not accurate or misunderstood because these references do not teach larger sequences cannot induce an antibody response or non-chemical synthesis were routinely used to make fragments and used for generating immune response.

Applicant's arguments have been fully considered but they are not deemed to be persuasive because although applicant argues that it is routine in the art to generate fragments and to determine whether or not those fragments are immunogenic and bind to an antibody, the claims are not drawn to encoded fragments consisting of SEQ.ID.NO:14 fragments. The requirements of 35 USC 112 first paragraph are drawn to teaching of how to make and use the claimed invention and are not drawn to generating immune response in order to determine whether or not the invention would function as claimed. In particular, screening assays (i.e., generating immune response) suggested by applicant do not enable the claimed invention because the court found in *Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004 that screening (routine) assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the claimed chemical invention.

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Applicant states that that the inventor's Declaration under 37 C.F.R. 1.132 indicates , the claimed composition is at least one true candidate against Chlamydia, and that the references (Allen et al Battereiger et al and Murdin et al) do not accurately show the state of the art and Dr. Murdin's declaration has weight in this respect. Applicant states that the examiner did not establish a reasonable basis to question the enablement provided for the claimed invention .

Applicant's arguments have been fully considered but they are not deemed to be persuasive because the examiner established the enablement rejection according Section 2164.04 of the MPEP using the state of the art with respect to vaccine preparation. However, the applicant has not shown evidence why the cited references are not accurate as one of the references cited in support of the enablement rejection is by the inventor Dr. Murdin.

Applicant again cites several BPAI's decisions for providing clear guidance on applying the courts' decisions to claims that recite sequence variants or fragments and the rejections are therefore incorrect.

This argument has been considered but is not persuasive for the reasons set forth above and because board decisions are reviewed and considered to the extent that they affirm the principles of the application of the statutory rejection set forth and each application is considered on its merits with the same principle. BPAI decisions do not carry presidential weight to the extent that they follow the principles laid down by CAFC.

Status of Claims

6. Claims 79-80 are objected to as being dependent upon a rejected base claim.

Claim 1,2, 4-17, 25, 36-38 and 81-83 are rejected.

Allowable subject matter:

An isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth

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in SEQ.ID.NO: 14, isolated vector comprising said nucleic acid, isolated host cell comprising said vector, and an immunogenic composition comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14.

Conclusion

7. **THIS ACTION IS MADE FINAL.** See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

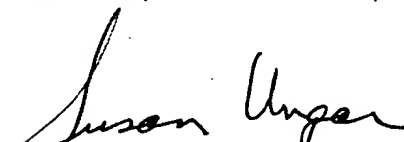
A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Padma Baskar Ph.D.